

FORM PTO-1390 (REV 11-2000)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER <b>159-64</b>
<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371</b>		U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5) <b>09/786,815</b>	
INTERNATIONAL APPLICATION NO. <b>PCT/JP00/04651</b>	INTERNATIONAL FILING DATE <b>12 July 2000</b>	PRIORITY DATE CLAIMED <b>12 July 1999</b>	
<b>TITLE OF INVENTION</b> <b>PHARMACEUTICAL COMPOSITION FOR TOPICAL ADMINISTRATION</b>			
<b>APPLICANT(S) FOR DO/EO/US</b> <b>TATARA et al.</b>			
<p>Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:</p> <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>2. <input checked="" type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</li> <li>4. <input type="checkbox"/> The U.S. has been elected by the expiration of 19 months from the priority date (Article 31).</li> <li>5. A copy of the International Application as filed (35 U.S.C. 371(c)(2)).             <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ol> </li> <li>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).             <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ol> </li> <li>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))             <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has <b>NOT</b> expired.</li> <li>d. <input type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</li> <li>10. <input type="checkbox"/> A English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</li> </ol> <p><b>Items 11 To 20 below concern document(s) or information included:</b></p> <ol style="list-style-type: none"> <li>11. <input type="checkbox"/> An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98.</li> <li>12. <input checked="" type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included.</li> <li>13. <input type="checkbox"/> A FIRST preliminary amendment.</li> <li>14. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment.</li> <li>15. <input type="checkbox"/> A substitute specification.</li> <li>16. <input type="checkbox"/> A change of power of attorney and/or address letter.</li> <li>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825.</li> <li>18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4).</li> <li>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</li> <li>20. <input type="checkbox"/> Other items or information.</li> </ol>			

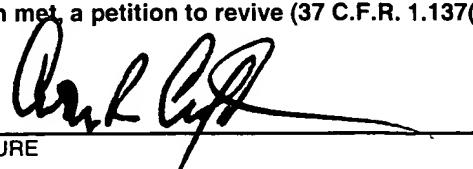
U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5) <b>09/786,815</b>	INTERNATIONAL APPLICATION NO. <b>PCT/JP00/04651</b>	ATTORNEY'S DOCKET NUMBER <b>159-64</b>																					
21. <input checked="" type="checkbox"/> The following fees are submitted:		<b>CALCULATIONS PTO USE ONLY</b>																					
<b>BASIC NATIONAL FEE (37 C.F.R. 1.492(a)(1)-(5)):</b> <ul style="list-style-type: none"> <li>-- Neither international preliminary examination fee (37 C.F.R. 1.482) nor international search fee (37 C.F.R. 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO .....\$1000.00</li> <li>-- International preliminary examination fee (37 C.F.R. 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO .....\$860.00</li> <li>-- International preliminary examination fee (37 C.F.R. 1.482) not paid to USPTO but international search fee (37 C.F.R. 1.445(a)(2)) paid to USPTO .....\$710.00</li> <li>-- International preliminary examination fee (37 C.F.R. 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4).....\$690.00</li> <li>-- International preliminary examination fee (37 C.F.R. 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4).....\$100.00</li> </ul>																							
<b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b>		\$      0.00																					
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 C.F.R. 1.492(e)).		\$      0.00																					
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>CLAIMS</th> <th>NUMBER FILED</th> <th>NUMBER EXTRA</th> <th>RATE</th> </tr> </thead> <tbody> <tr> <td>Total Claims</td> <td>20</td> <td>-20 =</td> <td>X      \$18.00</td> </tr> <tr> <td>Independent Claims</td> <td>3</td> <td>-3 =</td> <td>X      \$80.00</td> </tr> <tr> <td colspan="3"><b>MULTIPLE DEPENDENT CLAIMS(S) (if applicable)</b></td> <td>\$270.00</td> </tr> <tr> <td colspan="3"></td> <td style="text-align: right;"><b>TOTAL OF ABOVE CALCULATIONS =</b></td> <td style="text-align: center;">\$      0.00</td> </tr> </tbody> </table>		CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	Total Claims	20	-20 =	X      \$18.00	Independent Claims	3	-3 =	X      \$80.00	<b>MULTIPLE DEPENDENT CLAIMS(S) (if applicable)</b>			\$270.00				<b>TOTAL OF ABOVE CALCULATIONS =</b>	\$      0.00	
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			<b>TOTAL OF ABOVE CALCULATIONS =</b>	\$      0.00																			
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.		0.00																					
		<b>SUBTOTAL =</b>	\$      0.00																				
Processing fee of \$130.00, for furnishing the English Translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 C.F.R. 1.492(f)).		+      0.00																					
		<b>TOTAL NATIONAL FEE =</b>	\$      0.00																				
Fee for recording the enclosed assignment (37 C.F.R. 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). \$40.00 per property		+      40.00																					
Fee for Petition to Revive Unintentionally Abandoned Application (\$1240.00 – Small Entity = \$620.00)		\$      0.00																					
		<b>TOTAL FEES ENCLOSED =</b>	\$      40.00																				
		Amount to be: refunded      \$																					
		Charged      \$																					

a.  A check in the amount of \$40.00 to cover the above fees is enclosed.  
 b.  Please charge my Deposit Account No. 14-1140 in the amount of \$\_\_\_\_\_ to cover the above fees.  
     A duplicate copy of this form is enclosed.  
 c.  The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-1140. A duplicate copy of this form is enclosed.  
 d.  The entire content of the foreign application(s), referred to in this application is/are hereby incorporated by reference in this application.

**NOTE: Where an appropriate time limit under 37 C.F.R. 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. 1.137(a) or (b)) must be filed and granted to restore the application to pending status.**

**SEND ALL CORRESPONDENCE TO:**

NIXON & VANDERHYE P.C.  
 1100 North Glebe Road, 8<sup>th</sup> Floor  
 Arlington, Virginia 22201-4714  
 Telephone: (703) 816-4000

  
 SIGNATURE

**Arthur R. Crawford**  
 NAME

25,327      June 25, 2001  
 REGISTRATION NUMBER      Date

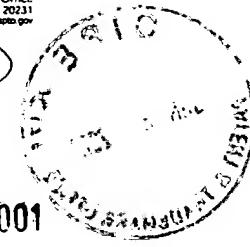
104-401  
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## UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents, Box PC-1  
United States Patent and Trademark Office  
Washington, D.C. 20231  
www.uspto.gov

U.S. APPLICATION NO.	FIRST NAMED APPLICANT	ATTY DOCKET NO.
09/786815	TATARA ET AL	159-64
NIXON & VANDERHYE 8TH FLOOR 1100 NORTH GLEBE ROAD ARLINGTON, VA 22201		INTERNATIONAL APPLICATION NO. PCT/JP00/04651
		I.A. FILING DATE 12 JUL 00
		PRIORITY DATE 12 JUL 99
DATE MAILED <b>26 APR 2001</b>		



## NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

1. The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as  a Designated Office (37 CFR 1.494)  an Elected Office (37 CFR 1.495):

U.S. Basic National Fee.  Indication of Small Entity Status.  
 Copy of the international application.  Translation of the international application into English.  
 Oath or Declaration of inventor(s).  Translation of Article 19 amendments into English.  
 Copy of Article 19 amendments.  Other:  
 Priority Document.  
 The International Preliminary Examination Report in English and its Annexes, if any.  
 Translation of Annexes to the International Preliminary Examination Report into English.

2.  Applicant has requested early processing under 35 U.S.C. 371(f) but has not filed the following indicated items and/or the indicated items in paragraph 3 below. The Basic National Fee and the copy of the international application must be filed prior to 20 or 30 months from the priority date to avoid abandonment.

U.S. Basic National Fee.  Copy of the international application.

3. The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

a. Translation of the application into English. A processing fee will be required if submitted later than the appropriate 20 or 30 months from the priority date.  
 The current translation is defective for the reasons indicated on the attached Notice of Defective Translation.  
 b. Processing fee for providing the translation of the application and/or the Annexes later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(f)).  
 c. Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), properly identifying the application (preferably by the International application number and international filing date). A surcharge will be required if submitted later than the appropriate 20 or 30 months from the priority date.  
 The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) for the reasons indicated on the attached PCT/DO/EO/917.  
 d. Surcharge for providing the oath or declaration later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(c)).

4. Additional claim fees of \$  as a  large entity  small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due (37 CFR 1.492(g)). See attached PTO-875.

5.  Applicant has not submitted the required sequence listing pursuant to 37 CFR 1.821-1.825. See attached PCT/DO/EO/920.

**ALL OF THE ITEMS SET FORTH IN 3(a)-3(d), 4 AND 5 ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 22 OR 32 MONTHS (where 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

6. If box 3a or 3c is checked, a translation of the Annexes **MUST** be submitted no later than the time period set above or the Annexes will be cancelled. A processing fee will be required if submitted later than 20 or 30 months from the priority date.  
7.  The Article 19 amendments are cancelled since a translation was not provided by the appropriate 20 (37 CFR 1.494(d)) or 30 (37 CFR 1.495(d)) months from the priority date.

Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above. (37 CFR 1.5)

*A copy of this notice MUST be returned with this response.*

Enclosed:  PCT/DO/EO/917  Notice of Defective Translation  
 PTO-875  PCT/DO/EO/920

Paulette Kidwell, Paralegal

Telephone: 703-305-3656

FORM PCT/DO/EO/905 (March 2001)

DOCKETED

CLT/MATTER # 159-64  
MAIL DATE April 26, 2001  
DUE DATE June 26, 2001  
FINAL DEADLINE NOV 26, 2001  
DOCKETED BY MR / MSS